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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------|-------------|----------------------|---------------------|------------------|
| 10/580,029 | 05/19/2006 | Yukako Fukuhira | Q95047 | 7517 |
| 23373 | 7590 | 06/25/2010 | EXAMINER | |
| SUGHRUE MION, PLLC | | | SCHULTZ, JAMES | |
| 2100 PENNSYLVANIA AVENUE, N.W. | | | | |
| SUITE 800 | | | ART UNIT | PAPER NUMBER |
| WASHINGTON, DC 20037 | | | 1633 | |
| | | | | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 06/25/2010 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/580,029 | FUKUHIRA ET AL. | |
| | Examiner | Art Unit | |
| | JD SCHULTZ, PhD | 1633 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 22 March 2010.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,3-6 and 8-17 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) 1, 3, 4, 6, 8-12, 16 and 17 is/are allowed.
 6) Claim(s) ____ is/are rejected.
 7) Claim(s) 5 and 13-15 is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>see action</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: ____ . |

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed March 22, 2010 has been considered. Rejections and/or objections not reiterated from the previous office action mailed September 21, 2009 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Allowability and Election/Restrictions

Claims 1, 3, 4, 6, 8-12, 16 and 17 are allowable. The restriction requirement between inventions, as set forth in the Office action mailed on January 10, 2008 and November 14, 2008, have been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.**

In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once a restriction requirement is withdrawn, the provisions of

35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim 11 is directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claim 11, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, is hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirements as set forth in the Office actions mailed on January 10, 2008 and November 14, 2008 are hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim Objections

Claims 5 and 13-15 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 5 recites that the phospholipid of claim 4 is L-a-phosphatidylethanolamine-dioleoyl. However, the phospholipid of claim 4 is phosphatidylethanolamine. While L-a-phosphatidylethanolamine-dioleoyl may be considered a derivative of phosphatidylethanolamine, it is not properly considered phosphatidylethanolamine since it has a different structure.

Amendment of claim 5 to depend from claim 3, which recites derivitives of phosphatidylethanolamine among others, would be remedial.

Claims 13-15 each depend on claim 1, which recites a substrate consisting essentially of a single polymer from a group, and a phospholipid. Claims 13-15 each recite the same substrate composed primarily of a specific polymer and a phospholipid. Since the base claim recites “consisting essentially of”, which is considered closed to all but those elements which don’t change the basic and novel features of the invention as discussed at M.P.E.P. 2111.03), while claims 13-15 recite “composed primarily of”, which is considered to be open to the inclusion of other elements, claims 13-15 are considered to improperly broaden the base claim. Amendment to recite “consisting essentially of” in claims 13-15 would be remedial.

Information Disclosure Statement

Applicants have requested that the IDS filed on June 23, 2009 be returned with an indication that U. S. Patent Number 5,716,413 and the Non-Patent Literature of Sato et al. have been considered. It appears that U. S. Patent Number 5,716,413 was considered but inadvertently overlooked in being initialed. A copy of this IDS indicating U. S. Patent Number 5,716,413 as having been considered is being furnished herewith.

Applicants have also requested that the reference of Sato, published in a foreign language, be indicated as considered, on the grounds that even though the reference is published in a foreign language, M.P.E.P. 609.04(a)(III) clearly addresses this situation, with an instruction to indicate the reference as considered:

Where the information listed is not in the English language, but was cited in a search report or other action by a foreign patent office in a counterpart foreign application, the requirement for a concise explanation of relevance can be satisfied by submitting an English-language version of the search report or action which indicates the degree of relevance found by the foreign office. This may be an explanation of which portion of the reference is particularly relevant, to which claims it applies, or merely an "X", "Y", or "A" indication on a search report.

This section of the M.P.E.P. appears directly on point. Given that the present examiner has no idea what the claimed subject matter in the counterpart application actually recites, and further does not read Japanese, no other basis exists for refusing to mark the reference as considered. Accordingly, the foreign language document of Sato has been indicated as considered on the accompanying IDS.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

/JD SCHULTZ, PhD/

Primary Examiner, Art Unit 1633